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APPLICATION NO.	FILING DATE	FIRST NAME INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/948,393	10/10/1997	DENISA D. WAGNER	CEBI-P02-002	6639

28720 7500 10/07/2002

ROPES & GRAY
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1641

DATE MAILED 10/07/2002

46

Please find below and/or attached an Office communication concerning this application or proceeding.



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1644

DATE MAILED: 04/08/2002

46

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Office Action Summary	Application No.	Applicant(s)	
	08/948393	WAGNER ET AL.	
	Examiner	Art Unit	
	GIMBEL	1644	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/31/02
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) _____ is/are pending in the application. 71-85
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected. 71-85
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Unamended Patent Drawing Review (PTO-946) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Applicant's amendment, filed 7/31/02 (Paper No. 46), has been entered.
Claims 1-24, 28-30, 35-38, 40, 42-70 and 75 have been canceled.
Claims 25-27, 31-34, 39 and 41 have been canceled previously

Claims 71 and 80 have been amended, according to the Marked-Up Claims.

Although the claims have been amended according to the Marked-Up Claims, it is noted that claims 71 and 80 do not indicate that they were amended and the recitation of claim 80 is not consistent with the Marked-Up Claims.

MPEP 714.22 specifies protocols for use in amending language in a pending claim.

Claims 71-74 and 76-85 are pending.

Claims 71-74 and 76-85 are under consideration as they read on the elected invention, drawn to methods of treating or inhibiting atherosclerosis with PSGL-1, fragments and chimeric constructs thereof.

As pointed out previously, the following is noted.

For examination purposes, the use of PSGL-1, fragments and chimeric constructs thereof have the inherent property of inhibiting L- / E-selectin-mediated interactions. If applicant disagrees with this assessment, then such claims would be removed from consideration as they read on the elected invention. Also, analogs of PSGL-1 read on fragments and chimeric constructs thereof.

If applicant disagrees with this assessment, then such claims would be removed from consideration as they read on the elected invention

For examination purposes, PSGL "on a leukocyte" (e.g. neutrophil, monocyte) reads on PSGL and not on the administration of cells per se.

Claims 71-74 and 76-85 as they read on methods of treating or inhibiting atherosclerosis with agents other than PSGL-1 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected invention.

Again, applicant is invited to provide a complete set of the pending claims for clarity, and preferably applicant is invited to amend or to cancel/add claims as they read on methods of treating or inhibiting atherosclerosis with PSGL-1 for clarity. The pending claims are spread over a number of amendments. Further, the claims have been restricted into Groups.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Office Action will be in response to applicant's arguments, filed 7/31/02 (Paper No. 46). The rejections of record can be found in the previous Office Action (Paper No. 44).

3. Upon reconsideration of applicant's canceled and amended claims, filed 7/31/02 (Paper No. 46), the previous rejections under 35 U.S.C. § 112, first paragraph, written description with respect to the recitation of "chimeric constructs of PSGL-1".

4. Claims 71-81, 83-85 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "fragments that inhibit the interaction between P-selectin and PSGL-1" and "analogs that read on "PSGL-1" or "fragments that inhibit the interaction between P-selectin and PSGL-1", does not reasonably provide enablement for any "fragment" or "analog" of PSGL. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims for the reasons set forth in Paper No. 44.

Applicant's arguments, filed 7/31/02 (Paper No. 46), have been fully considered but are not found convincing essentially for the reasons of record.

As applicant notes, the examiner has acknowledged that the specification is enabling for "fragments that inhibit the interaction between P-selectin and PSGL-1" and "analogs that read on "PSGL-1" or "fragments that inhibit the interaction between P-selectin and PSGL-1".

Applicant also relies on page 7, lines 30-35 to support fragments and analogs which inhibit P-selectin and ligand binding.

However, the claims do not recite the functional language "inhibit the interaction between P-selectin and PSGL-1" to define said fragments and analogs (mimetics).

Amending independent claim 71 to recite the functional language "inhibit the interaction between P-selectin and PSGL-1" would obviate this rejection for the reasons of record set forth in Paper No. 44.

Applicant's arguments are not found persuasive.

5. Claims 71-82 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Cummings et al. (U.S. Patent No. 5,464,778) (see entire document) for the reasons set forth in the previous Office Action (Paper No. 44) and addressed herein.

Claims 71-85 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cummings et al. (U.S. patent No. 5,464,778) in view of Larsen et al. (U.S. Patent No. 5,840,679) for the reasons set forth in the previous Office Action (Paper No. 44) and addressed herein.

Applicant's arguments, filed 7/31/02 (Paper No. 46), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that neither Cummings et al. nor Larsen et al. Recognize the role of P-selectin in the formation of atherosclerotic lesions or teach the use of PSGL to prevent the formation of the lesions to prevent atherosclerosis. It is acknowledged that pages 1-2 of the instant specification discloses the art known role of leukocyte binding to endothelial cells in the lumen of the artery wall in the lesions known as fatty streaks at the time the invention was made.

Applicant asserts that it was applicant who discovered that P-selectin is involved in the formation of atherosclerotic lesions and that a therapeutic agent which inhibits the binding of P-selectin and P-selectin ligand can be used to treat atherosclerosis.

Although applicant asserts that the prior does not recognize any relationship between inflammation and atherosclerosis, pages 1-2 of the instant specification discloses the art known role of leukocyte binding to endothelial cells in the lumen of the artery wall in the lesions known as fatty streaks at the time the invention was made.

Applicant asserts that there was no connection between atherosclerosis and other unrelated disease mentioned in the references and that there was no motivation or reasonable expectation that such a treatment would have succeeded.

In contrast to applicant's assertions, it was well known by the ordinary artisan that leukocyte-endothelial interactions were involved in a number of immune responses and inflammatory responses and conditions at the time the invention was made.

More pointedly with respect to the instant claimed methods, again it is noted that Cummings et al. teach the use of PSGL in the treatment of leukocyte adherence, inflammation and coagulation, including ischemia-reperfusion injury and atherosclerosis (see column 18, paragraphs 5-8; columns 19-20, overlapping paragraph).

Therefore, applicant's arguments are not found persuasive for the reasons of record.

6. Claims 71-85 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 40-41, 45, 49-52, 56, 59-60, 73-74 (or appropriate pending claims) as they read on the use of PSGL-1 to treat atherosclerosis of copending application Serial No. 09/436,076 and

claims 39-88 (or appropriate pending claims) as they read on the use of PSGL-1 to treat atherosclerosis of copending application USSN 09/883,642 for the reasons of record set forth in Paper No. 44.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same or nearly the same methods of treating atherosclerosis with the same or nearly the same PSGL-1, fragments and chimeric constructs thereof.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's amendment, filed 7/31/02 (Paper No. 46), indicates that applicant is prepared to file a terminal disclaimer in this application to overcome this rejection provided that the application is otherwise considered to be in proper condition for allowance.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Serial No. 08/948393
Art Unit 1644

-6-

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
October 7, 2002